

Remarks:

In the Office Action mailed on September 11, 2008, the Examiner rejected claims 1-6 and objected to claims 4 and 5. Claims 1-6 are pending in the application.

In the Specification

Applicant has submitted an amended Abstract. The changes made to the Abstract were simply to conform to usual U.S. practice and are closely tailored to the invention as claimed. No new matter has been added.

Status of the Claims

Claims 1-6 were rejected in the Office Action. Claims 4-5 were objected to. Claims 4 and 5 are amended herein. Claims 1-6 are now pending in the application.

The Claims

Claim Objections

Claims 4-5 are objected to by the Examiner for the following informalities: it appears as if “syringes bodies” in the 3rd line of Claims 4-5 should read “syringe bodies”. Applicants had previously amended Claims 4-5 to correct the informality in the Office Action dated May 8, 2008. Applicant’s feel the amendment made in the May 8, 2008 response may have been overlooked due to the fact that the change was very slight. Applicants hereby re-submit the amendments made to Claims 4 and 5. In light of the claim amendments, Applicant’s respectfully request withdrawal of the objection to claims 4-5.

35 USC 103

Claims 1-6 were rejected under 35 U.S.C. 103(a) as unpatentable over Fuji (XP-002198180 hereinafter “Fuji”) in view of Schwartz (WO 92/04976 hereinafter “Schwartz”). Applicants traverse the rejection.

Claim 1 recites “[a] column for flash chromatography comprising spherical and porous silica gel having granules comprised between 3 and 45 μm and pores comprised between 30 and 300 \AA ” and Claim 2 recites “[a] column for flash chromatography with semi-spherical and porous silica gel having granules comprised between 3 and 45 μm and pores comprised between 30 and 300 \AA .¹”

As the Examiner has noted “Fuji does not explicitly disclose granules comprised between 3 and 45 μm (Claim 1 and 2) or semi-spherical gel (claim 2)” (Office Action, Page 4, Numbered Paragraph 7). The Examiner turns to Schwartz for that teaching. (Office Action, Page 4, Numbered Paragraph 8).

The analysis for determining whether a claim is obvious under 103 includes (1) determining the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, and (3) the level of ordinary skill in the pertinent art. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18, 148 USPQ 459, 467 (1966); *KSR v. Teleflex* (82 USPQ2d 1385, 1391 (2007)). Furthermore, Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. *Graham*, 383 U.S. 1, 17–18, 148 USPQ 459, 467 (1966).

“As is clear from cases such as Adams, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR v. Teleflex*, 82

USPQ2d 1385, 1396 (2007)). As further noted in *KSR*, when examining a patent application that claims an innovation that is a combination of known teachings it is important to identify a reason that would have prompted a person to combine the elements in the way the claimed new invention does because inventions in most, if not all, instances rely on existing building blocks and will almost of necessity, be combinations of what already exists.

“Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, at 1397.

Applicant disagrees with the conclusion that it would have been obvious to combine Fuji and Schwartz.

As noted in the accompanying Declaration of Mr. Pascal Aznar (the inventor) a desirable characteristic of flash chromatography systems is the reduction of the pressure requirement on pumps used to put a sample to be separated through a chromatography column. The back pressure produced by the packing material affects the necessary driving pressure. It has been the experience in the industry that small silica particles, i.e., those less than 40µm, when packed in chromatography columns have a backpressure that is undesirably high and it had at the time of the invention become generally accepted that the use of particles with such a small particle size was detrimental to practical operation of liquid chromatography systems.

Accordingly, a person of ordinary skill in the art, knowing what such a person would know of the impact of small particle size to back pressure, would not be motivated to combine the teaching of Schwartz with Fuji.

A *prima facie* case of obviousness may be rebutted with evidence of long-felt need and of unexpected results, *In re Sullivan*, 84 USPQ2d 1034, 1038 (Fed. Cir. 2007); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1369; 82 USPQ2d 1321 (Fed. Cir. 2007). As discussed by Mr. Aznar in his declaration, there is a continuing desire in the art of flash chromatography to improve the resolution of the separation of materials found in a given sample as indicated by a theoretical plate number. This continuing desire to improve resolution of flash chromatography systems constitutes a long-felt need.

As set forth by Mr. Aznar, an unexpected result of the claimed invention is that the back pressure is sufficiently low to allow for the use of glass and plastic columns while maintaining a high resolution of the separation.

As further discussed in the Declaration of Mr. Aznar, an experiment was performed using equipment as used in Fuji with the claimed granule size, shape, and pores. These experiments reveal significant improvement over the results in Fuji. Given that there is a desire to improve the resolution of separation achieved by flash chromatography systems, the existence of spherical particles of a size as set forth in Schwartz, and the highly successful experimental results obtained by using a combination of the equipment of Fuji and the claimed granules, it follows that had the combination of Fuji and Schwartz been obvious a person of ordinary skill in the art would have already made the particle size substitution and reported similarly good results. However, because adopting the small particle size is counter-intuitive to a person of ordinary skill in the art, given the undesirably high level back pressure hitherto associated with the reduction of particle size, a person of ordinary skill in the art would not be motivated to make the combination of Fuji and Schwartz. Therefore, the invention as claimed is not obvious.

The Examiner suggested that “in order to obtain a flash chromatography column with high-strength silica that can be operated at a lower pressure because of the larger particle size” (Office Action, Page 4, Numbered Paragraph 10) as the reasoning behind the proposed combination of Fuji and Schwartz. That statement is illogical. Schwartz discloses a *smaller* particle size than that disclosed in Fuji. A *smaller* particle size causes a *higher* back pressure and thus increases the pressure requirement on a chromatography system. Accordingly, as discussed above, a person of ordinary skill in the art would expect that the smaller particle size of Schwartz would produce a pressure requirement higher than desirable. Therefore, the Examiner has not provided a clear rationale for the proposed combination of Fuji and Schwartz as required by *KSR* at 1396, quoting, *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329 (CA Fed. 2006).

Thus, for the reasons given above, Applicants respectfully request withdrawal of the rejection of Claims 1 through 6 and their early allowance.

The application is now deemed to be in condition for allowance and notice to that effect is solicited.

CONCLUSION

It is submitted that all of the claims now in the application are allowable. Applicants respectfully request consideration of the application and claims and its early allowance. If the Examiner believes that the prosecution of the application would be facilitated by a telephonic interview, Applicants invite the Examiner to contact the undersigned at the number given below.

Applicants respectfully request that a timely Notice of Allowance be issued in this application.

Respectfully submitted,

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